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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,499	02/13/2002	Evangelyn C. Alcilja	MSU 4.1-587	4246

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EXAMINER

LUM, LEON YUN BON

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,499

Applicant(s)

ALOCILJA ET AL.

Examiner

Leon Y. Lum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-10, 14-16, 18, 19, 21, 22, 24 and 26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-10, 14-16, 18, 19, 21, 22, 24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-2, 7-9, 14-16, 18-19, and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biosensor & Bioelectronics (2000), vol. 14, pp. 907-915) in view of Sigal et al (US 6,319,670 B1).

In the instant claims, Kim et al teach a conductimetric immunosensor design comprising a middle section that contains screen-printed thick film electrodes in an interdigitated structure, wherein antibodies are immobilized on the interdigitated area comprising silver electrodes (i.e. first zone contains a first capture agent in a defined area), wherein an anode and cathode are separated and the binding complex on the interdigitated structure is formed in between the electrodes (i.e. between electrodes on different sides of the defined area). See page 911, right column, 1st full paragraph, lines 1-5; and Figure 3, and caption. In addition, Kim et al teach that the immunosensor comprises a lower section that is defined with immobilized antibody-gold conjugates, wherein the lower section is a glass fiber membrane for sample application (i.e. a second of the zones containing a fluid transfer medium and a second capture reagent), and wherein the gold embodiment of the antibody-gold conjugates contain polyaniline as a conducting polymer (i.e. bound to an electrically conductive polymer), wherein the polyaniline is created by a standard procedure of oxidative polymerization of aniline monomer in the presence of APS (i.e. polymer formed by oxidative polymerization of monomers). See page 909, left column, 2nd paragraph; page 911, right column, 2nd full

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paragraph, lines 1-7; and Figures 1 and 3-4, and captions. Furthermore, Kim et al teach that after the immunostrips are placed in microwells, solutions within the microwells are absorbed from the bottom of the strips, wherein the medium dissolved the gold conjugate, reaction between the conjugate and the analyte took place to produce a complex, the complex was carried up into the next membrane with the immobilized binder (i.e. complex migrates to the first zone), and a second antigen-antibody reaction formed a sandwich-type immune complex at the gold surfaces, wherein a meter was used to measure the conductivities as responses of the immunostrips with the electrodes to variable analyte concentrations (i.e. alter the conductivity of the defined area to detect the analyte). See page 909, right column, and 2nd full paragraph to page 910, left column, 1st paragraph.

However, Kim et al fail to teach that the complex is formed in an absence of electrically conductive particles such that the polymer has been mixed to react with the second capture reagent. Note: The independent claims of the application have been amended to include the phrase "a second capture reagent bound to an electrically conductive polymer...wherein there is an absence of electrically conductive particles." Because the "electrically conductive *polymer*" is distinguished from the "electrically conductive *particles*," the "polymer" must either be (1) a different material or (2) a different shape or size from the "particles." The specification only supports electrically conductive embodiments that are polymers; no other materials, including metal, are included as the electrically conductive embodiment in the present invention. The polymer and particles must therefore be distinct in either shape or size; there would

otherwise be a new matter and an enablement and/or written description problem due to a lack of support and direction in the specification on how to apply non-polymer electrically conductive materials to the claimed invention. The claims are therefore interpreted as claiming "particles" that are different in shape or size from the "polymer."

Sigal et al teach that it is generally known in the art to create microparticles using conductive material from a variety of alternative sources, including metals such as gold, and organic polymers such as polyaniline, and wherein the microparticles can be entirely composed of a single or a mix of the conductive materials. See column 4, line 52 to column 5, line 32. In addition, Sigal et al teach that it is possible to attached ligands on the outer surface of a microparticle, regardless of the microparticle's composition. See column 4, lines 40-51. Furthermore, Sigal et al teach that the microparticles have a wide variety of sizes and shapes, including spherical, oblong, rod-like, or irregular. See column 5, lines 33-38.

Although Kim et al fail to teach that the complex is formed in the absence of electrically conductive particles, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute an organic polyaniline polymer for the gold particle, since Sigal et al teach that electrically conductive microparticles are interchangeable in material, shape, and size, and are all suitable for the same purpose. Furthermore, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. In addition, one of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in

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substituting polyaniline polymer in a non-spherical form, as taught by Sigal et al, for the gold bead of Kim et al, since the polyaniline microparticles of Sigal et al are able to immobilize biomolecules, thereby allowing the microparticles to accomplish the binding functions required by Kim et al, and since the polyaniline microparticles of Sigal et al would also be able to immobilize the polyaniline polymer strands on the microparticle surface, thereby allowing the microparticles of Sigal et al to perform the conducting functions required by Kim et al.

With regards to claims 2, 9, and 15, Kim et al teach a cellulose membrane that is an absorption pad as an upper section of the immunosensor strip (i.e. third zone adjacent to the first zone). See Figures 1 and 3, and captions.

With regards to claims 16, 18-19, and 21, Kim et al teach microwells with sample medium into which the immunostrips were placed (i.e. third zone or pad is applied), as stated above. See page 909, 2nd full paragraph, lines 8-18; and Figure 1 and caption. Since the term "pad" has not been defined in the specification, the instant term is considered to be any substrate capable of containing a liquid sample medium.

With regards to claims 7 and 14, Kim et al also teach that voltage was applied across the electrodes (i.e. electrical means) and that conductimetric detection was performed by a conductivity meter, wherein the measurements can determine a transient response after complex formation between antigen and antibody (i.e. measuring means for determining a change in the conductivity of the first area between and after application of the sample). See page 910, left column, 1st paragraph, lines 5-8; and page 912, right column, 2nd full paragraph, lines 1-4.

5. Claims 3, 10, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biosensor & Bioelectronics (2000), vol. 14, pp. 907-915) in view of Sigal et al (US 6,319,670 B1) as applied to claims 1, 8, and 14 above, and further in view of Roberts et al (US 5,958,791).

Kim et al and Sigal et al references have been disclosed above, but fail to teach a multiple array of first zones each having a first capture reagent with a different specificity to immobilize one of multiple analytes (claims 22, 24, and 26), and also fail to teach that the first defined area has a dimension between the electrodes of 1.0 mm (claims 3 and 10).

Roberts et al reference teaches a test device that includes multiple sets of interdigitated electrode arrays with an area of 6mm x 1mm, in order to perform simultaneous multiple analyte detection and assay a test sample for a plurality of analytes. See column 18, lines 53-55; column 24, lines 1-6; and column 25, lines 16-20. In addition, Roberts et al teach that the test device is a test strip with capillary flow through an absorbent material with a capture region, wherein the capture region contains binding material that can be an antibody. See column 5, lines 29-42 and 55-56; column 11, lines 29-40; and Figure 1.

It would have been obvious at the time of the invention to modify the method of Kim et al and Sigal et al with a test device that includes multiple sets of interdigitated electrode arrays with an area of 6mm x 1mm, as taught by Roberts et al, in order to perform simultaneous multiple analyte detection and assay a test sample for a plurality

of analytes. The electrode arrays of Roberts et al have the advantage of allowing multiple tests to be performed at once, thereby cutting down on experimentation time, and providing motivation for combining the electrode arrays with the device of Kim et al and Sigal et al. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in including multiple sets of interdigitated electrode arrays with an area of 6mm x 1mm, as taught by Roberts et al, in the device of Kim et al and Sigal et al, since Kim et al and Sigal et al teach a test strip with an antibody-layered capture region on an interdigitated electrode wherein sample can flow up the strip, and the interdigitated electrode arrays of Roberts et al also include a capture region with immobilized antibody, and are on a test strip that can accommodate capillary flow.

In regards to claim 26, since Kim et al, Sigal et al, and Roberts et al in combination teach a device comprising an array of interdigitated electrodes, the intended use limitation "multiple analytes can be detected simultaneously from the sample by providing a constant current and measuring generated voltages across the area of each of the first zones" is fully capable of being performed by the device.

Conclusion

6. No claims are allowed.

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on weekdays from 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1641



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